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Science Policy Note SPN2016-01

Restricted Use of Human Studies with Pesticides for Regulatory Purposes

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This Science Policy Note is to update stakeholders on Health Canada's Pest Management Regulatory Agency's (PMRA's) approach on using data from pesticide studies conducted with human participants, for regulatory purposes. These studies are undertaken by pesticide applicants, registrants and third party laboratories and researchers under very limited circumstances. Examples include, but are not limited to: those addressing systemic health effects, non-systemic health effects (for example, skin irritation), pharmacokinetics, exposure and insect repellent efficacy. Although considered as a type of human study, epidemiology studies and passive biomonitoring studies with pesticides are not the subject of this note as they do not involve intentional exposure.

The PMRA does not use systemic toxicity studies conducted with human participants in the course of assessment of new pesticide registration submissions or in re-evaluations. Systemic toxicity studies are typically designed to measure minor reversible effects; however, the development of an adverse biological response cannot be precluded in these studies. The underlying objective of determining a point of departure for a measurable effect in these studies could not only endanger the health of a participant, it could also be considered as being contrary to the best interests of the participant. These studies, by design, are rarely, if ever, undertaken to protect human health and raise significant safety and ethical issues.

The remaining types of studies conducted with human participants (i.e. non-systemic toxicity, pharmacokinetics, exposure and insect repellent efficacy) will continue to be considered during the evaluation of a pesticide. These studies will be assessed for ethical conduct (i.e. requirement for the studies to be approved by an independent institutional review board (IRB) or research ethics board (REB)) in addition to scientific acceptability. Pesticide studies conducted with human participants are infrequently undertaken in Canada. Nonetheless, the PMRA has identified key elements required for such studies, which are outlined below. The development of these elements has been guided by the principles of Canada's Tri-Council Policy Statement, Second Edition (TCPS-2), as well as USEPA's Final Rule on Protections for Subjects in Human Research.

Foremost among these elements is the requirement of independent IRB approval for ensuring ethical conduct of the research. It is the researcher's responsibility to obtain approval of an IRB. The letter of approval from the researcher's IRB and the supporting experimental protocol are required to be submitted to the PMRA with the appropriate documentation for research authorization. The PMRA is now extending the requirement of IRB approval to all human studies with pesticides that will be conducted in Canada. If the protocol has been accepted by the US Human Studies Review Board,[1] proof of this acceptability will expedite this aspect of the assessment.

Research undertaken in Canada should adhere to the tenets of the TCPS-2,[2] particularly those addressing the welfare of study participants, informed consent and inclusion/exclusion criteria. In addition, the PMRA is requiring additional measures for studies conducted with pesticides.

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1 http://www2.epa.gov/osa/human-studies-review-board

2 http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

These measures include i) excluding the participation of pregnant and lactating women and children in research; ii) excluding the participation of non-autonomous individuals in research; and, iii) requiring a physician who is entitled to provide health care under the laws of the province and is a member in good standing of a professional medical association to be involved with the research (for example, by providing medical oversight).

Studies involving human participants that are conducted outside of Canada and submitted to the PMRA must be consistent with the tenets of the TCPS-2 and PMRA requirements.

Any questions regarding this policy note should be directed to the PMRA's Pest Management Information Service.

Pest Management Information Service

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